REMARKS

I. Rejections to Claims in the Office Action

The Office Action mailed August 11, 2005 rejects claims on the following bases:

(1) Claims 7-14 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement;

(2) Claims 4-6 and 10-14 were rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;

(3) Claims 7-14 were rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility;

(4) Claims 1-2 and 4 were rejected under 35 U.S.C. 102(b) as being anticipated by Nardella (5,713,896);

(5) Claims 1-2 and 4-6 were rejected under 35 U.S.C. 102(b) as being anticipated by Sherman (5,971,980); and

(6) Claim 3 was rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman or Nardella in view of Chia et al. (5,913,856).

Each of the foregoing rejections is responded to below, where each response references the number corresponding to each rejection set forth above.

II. Response to Rejections Made in the Office Action

(1) <u>Claims 7-14 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.</u>

The Office Action stated that the claimed phrase "impedance measuring electrode" was not found in the specification. Although this deficiency does not necessarily preclude examination of claims 1-6 because the Examiner has inferred its meaning, claim 7 includes language toward a "second" impedance measuring electrode that is interconnected with a first

impedance measuring electrode and a first and second ablation means. Applicant is advised to clarify, without adding new matter, where in the specification exists two ablation means and two impedance measuring electrodes.

In response, the Applicants would like to point out in the specification the following: "In the context of R-F ablation, measurement of impedance may be done using the ablation electrodes or may be done using dedicated electrodes adjacent to the ablation electrodes. In the context of the other types of ablation discussed above, impedance measurement would typically be accomplished by means of a dedicated set of impedance measurement electrodes" (see page 4, lines 3-8). "Impedance may be measured between the ablation electrodes or between electrodes located adjacent the ablation electrodes" (see page 10, lines 22-23). "Measurement of impedance in tissue associated with the electrode pair may be made using the ablation electrodes themselves or electrodes located in proximity to the ablation electrodes" (see page 12, lines 3-5). "After initialization at 200, the microprocessor 800 (Fig. 4) initiates delivery of ablation energy at 201 and causes the impedance measurement circuitry associated with the electrode or electrode pair being evaluated or derives impedance based on applied voltage and current as discussed above to acquire a base line or initial impedance Z_i , which may be, for example the maximum impedance during the first three seconds of ablation" (see page 12, lines 8-13). "In the same fashion as for Figures 5a and 5b, the procedure defined by the flow chart of Figure 6 it should be understood to be employed in conjunction with an impedance measurement circuit with a single electrode pair, which procedure would be repeated for other electrodes or electrode pairs, if present" (see page 14, lines 24-29). "Figure 7 is a function flow chart illustrating the over-all operation of the device in conjunction with a multi electrode or multi electrode pair ablation apparatus. In the flow chart of Figure 7, all the electrodes are activated simultaneously and individual electrodes or electrode pairs are deactivated in response to impedance measurements associated with the electrode pair indicating that the lesion formed between that electrode pair is completely transmural" (see page 16, lines 27-31 and page 17, line 1). Therefore, the rejection of claims 7-14 as failing to comply with the enablement requirement should be withdrawn.

(2) Claims 4-6 and 10-14 were rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action stated that the Applicant neglects to positively recite any new structure in these claims. "Detecting", "initiating", "employing" and "responding" as claimed are steps in a method and do not add any new structure to the invention.

In response, the Applicants would like to point out that claims 4 and 7 require that the first ablation electrode and the impedance measuring electrode be the same electrode and that claims 5, 6, 11 and 12 require that the control circuitry comprises a processor. Therefore, the rejection of claims 4-6 and 10-12 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention should be withdrawn.

(3) Claims 7-14 were rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The Office Action stated that the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The phrase "impedance measuring electrode" is not found in the specification.

In response, the Applicants would again like to point out in the specification the following: "In the context of R-F ablation, measurement of impedance may be done using the ablation electrodes or may be done using dedicated electrodes adjacent to the ablation electrodes. In the context of the other types of ablation discussed above, impedance measurement would typically be accomplished by means of a dedicated set of impedance measurement electrodes" (see page 4, lines 3-8). "Impedance may be measured between the ablation electrodes or between electrodes located adjacent the ablation electrodes" (see page 10, lines 22-23). "Measurement of impedance in tissue associated with the electrode pair may be made using the ablation electrodes themselves or electrodes located in proximity to the ablation electrodes" (see page 12, lines 3-5). "After initialization at 200, the microprocessor 800 (Fig. 4) initiates delivery of ablation energy at 201 and causes the impedance measurement circuitry associated with the electrode or electrode

pair being evaluated or derives impedance based on applied voltage and current as discussed above to acquire a base line or initial impedance Z_i , which may be, for example the maximum impedance during the first three seconds of ablation" (see page 12, lines 8-13). "In the same fashion as for Figures 5a and 5b, the procedure defined by the flow chart of Figure 6 it should be understood to be employed in conjunction with an impedance measurement circuit with a single electrode pair, which procedure would be repeated for other electrodes or electrode pairs, if present" (see page 14, lines 24-29). "Figure 7 is a function flow chart illustrating the over-all operation of the device in conjunction with a multi electrode or multi electrode pair ablation apparatus. In the flow chart of Figure 7, all the electrodes are activated simultaneously and individual electrodes or electrode pairs are deactivated in response to impedance measurements associated with the electrode pair indicating that the lesion formed between that electrode pair is completely transmural" (see page 16, lines 27-31 and page 17, line 1). Therefore, the rejection of claims 7-14 as being not supported by either a specific and substantial asserted utility or a well established utility since the phrase "impedance measuring electrode" was not found in the specification should be withdrawn.

(4) <u>Claims 1-2 and 4 were rejected under 35 U.S.C. 102(b) as being anticipated by Nardella (5,713,896)</u>.

The Office Action stated claims 1-2 and 4 were anticipated by Nardella (5,713,896). Nardella discloses a system comprising active and return electrodes associated with an electrosurgical tool, an impedance monitoring device and a power control unit, which adjusts the energy applied to tissue to maintain tissue impedance within a preselected and desired range (see abstract). Upon delivery of electrosurgical energy to tissue through the active electrode, a measurable current is conveyed through the return electrode for use by the impedance monitor, where tissue impedance is determined. As more tissue comes into contact with the active electrode, the current at the return electrode decreases. The impedance monitor measures this as an increase in impedance and conveys a signal representative of the measured impedance to the control module, which in turn makes any necessary increase in the voltage conveyed to the active electrode to maintain tissue impedance within a desired range. Where the impedance monitor detects a decrease in tissue impedance below the desired minimum, the power control module

decreases the applied electrosurgical energy to maintain tissue impedance in the desired range (see col. 4, lines 35-50).

A rejection based on anticipation under 35 U.S.C. 102 requires all of the elements recited in the claims of the invention to be found within the four corners of the cited reference. Claims 1-2 and 4 require a control circuitry operably coupled to a generating means to initiate and terminate the application of ablating energy to a first ablating means, wherein the control circuitry is coupled to the impedance measurement circuit and terminates application of ablation energy to the first ablating means responsive to occurrence of an impedance plateau measured by the impedance measuring circuitry using a first impedance measuring electrode, following initiation of application of ablating energy to the first ablating means. Nardella never discloses such a control circuitry. Nardella discloses circuitry that makes changes to the voltage conveyed to an active electrode to maintain tissue impedance within a desired range. Nardella does not disclose circuitry that terminates the application of ablation energy to a first ablating means responsive to occurrence of an impedance plateau. Thus the U.S.C. 102(b) rejection for claims 1-2 and 4 as being anticipated by Nardella should be withdrawn.

(5) Claims 1-2 and 4-6 were rejected under 35 U.S.C. 102(b) as being anticipated by Sherman (5,971,980).

The Office Action stated claims 1-2 and 4-6 were anticipated by Sherman (5,971,980). Sherman discloses that impedance may be used to control the proper duty cycle for an ablation procedure. Too great a rise in the impedance may indicate that charring of the tissue has begun, in which case the control processor will lower the duty cycle of the power output from the ablation generator. In a case where the impedance increases to a predetermined threshold, such as twenty-five percent above the initial impedance, the ablation power is interrupted and the ablation procedure stopped. The impedance change is monitored in percentage units in one embodiment, and the relative impedance rise is considered (see col. 7, lines 10-23). In one embodiment, an impedance switch permits the user to select the percentage rise in impedance at which point the processor automatically discontinues the application of ablation energy (see col. 8, lines 20-28).

A rejection based on anticipation under 35 U.S.C. 102 requires all of the elements recited in the claims of the invention to be found within the four corners of the cited reference. Claims 1-2 and 4-6 require a control circuitry operably coupled to a generating means to initiate and terminate the application of ablating energy to a first ablating means, wherein the control circuitry is coupled to the impedance measurement circuit and terminates application of ablation energy to the first ablating means responsive to occurrence of an impedance plateau measured by the impedance measuring circuitry using a first impedance measuring electrode, following initiation of application of ablating energy to the first ablating means. Sherman never discloses such a control circuitry. Sherman discloses circuitry that monitors impedance and discontinues the application of ablation energy based on an impedance rise. Sherman does not disclose circuitry that terminates the application of ablation energy responsive to an occurrence of an impedance plateau. Generally, a plateau is a relatively stable or quiescent period or state. Therefore, a rising impedance (e.g., beyond a predetermined threshold) is not an impedance plateau. Thus the U.S.C. 102(b) rejection for claims 1-2 and 4-6 as being anticipated by Sherman should be withdrawn.

(6) <u>Claim 3 was rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman or Nardella in view of Chia et al. (5,913,856)</u>.

The Office Action stated claim 3 was unpatentable over Sherman or Nardella in view of Chia et al. Nardella discloses circuitry that makes changes to the voltage conveyed to an active electrode to maintain tissue impedance within a desired range. Sherman discloses circuitry that monitors impedance and discontinues the application of ablation energy based on an impedance rise. Chia et al. discloses an ablation catheter having fluid infusion and irrigation means. The flow rate of fluid is controlled to optimize the cooling effect of the energy delivering electrode of the catheter (see col. 3, lines 59-64). The impedance usually rises at the tissue contact site when RF energy is delivered through an electrode (see col. 1, lines 62-63). The fluid is continuously or intermittently supplied to evenly cover and rinse the electrode so that the impedance rise at the contact site is substantially reduced (see col. 3, lines 25-29). A control system regulates the flow rate based on signals representative of the tissue impedance (see col. 3, lines 62-64).

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Together the Nardella reference, the Sherman reference and the Chia et al. reference do not provide any motivation, suggestion or teachings for a control circuitry operably coupled to a generating means to initiate and terminate the application of ablating energy to a first ablating means, wherein the control circuitry is coupled to the impedance measurement circuit and terminates application of ablation energy to the first ablating means responsive to occurrence of an impedance plateau measured by the impedance measuring circuitry using a first impedance measuring electrode, following initiation of application of ablating energy to the first ablating means as required in claim 3. Sherman, Nardella and Chia et al. never disclose circuitry that terminates the application of ablation energy responsive to an occurrence of an impedance plateau. Therefore, the rejection of claim 3 based on Sherman or Nardella in view of Chia et al. should be withdrawn.

Support for this amendment is clearly found in the application as originally filed. No new matter is presented.

Examination and reconsideration of the application as amended is requested. After adding the claims as set forth above, claims 1-20 are pending in the application and are now believed to be in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

A request for a three (3) month extension of time under 37 C.F.R. 1.136(a) has been filed with this amendment. Please charge to Deposit Account No. 13-2546 the fee of $1020.00 which is required for the three-month extension of time.

A supplemental information disclosure statement has been filed with this response. Please charge to Deposit Account No. 13-2546 the fee of $180.00 which is required for the information disclosure statement.

If any additional fee is required in connection with these papers, please charge such fee to Deposit account No. 13-2546.

If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is urged to contact the undersigned agent at 763-391-9867.

Date 2/9/06

By

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